Baker's Best Health Products, Inc. 4/25/18

Chicago District Office
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WARNING LETTER
FY18-HAFE6-06

April 25, 2018

Jeffery Baker, President and Kim A. Gasior, Vice President
Baker’s Best Health Products, Inc.
46925 West Road
Wixom, MI 48393

Dear Mr. Baker and Mr. Gasior:

On December 13, 2017 through December 20, 2017, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, located at 46925 West Road, Wixom, MI. During the inspection we collected labels and labeling for your products. Based on a subsequent review of your product labels and labeling collected during the inspection, including mailed pamphlets, and your website at www.bakersbesthealth.com, we have identified serious

violations of the Federal Food, Drug, and Cosmetic Act (the Act) and applicable regulations. As explained below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act. You can find the Act and FDA regulations through links on FDA's home page at **www.fda.gov (http://www.fda.gov)**.

Unapproved New Drugs

FDA reviewed your website at the Internet addresses www.bakersbesthealth.com in March 2018 and has determined that you take orders there for the products Colon Formula, Eterni-D, Triple Action Joint Formula, and Apple Cider Vinegar+ . FDA also reviewed the mailed pamphlets for Colon Formula, Eterni-D, Triple Action Joint Formula, and Apple Cider Vinegar + collected during the inspection of your facility between December 13, 2017 and December 20, 2017. The claims on your website and other product labeling establish that the products are drugs under Section 201(g)(1)(B) of the Act [21 U.S.C. §321(g)(1)(B)] because they are intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering these products for introduction into interstate commerce for such uses violates the Act.

Examples of some of the website and other labeling claims that provide evidence that your products are intended for use as drugs include:

Eterni-D

Website claims-
"This breakthrough blend combines three highly effective ingredients that can help fight high blood pressure, high blood sugar levels … constipation, obesity ...."

Mail pamphlet claims-
"FOS. This prebiotic helps relive digestive problems like gas, bloating, constipation, and diarrhea"
"Vitamin D—The Sunshine Vitamin… Reduces cancer risk"

Triple Action Joint Formula

Website claims-
"Nourish joints to reduce aches and discomfort"
"Supports increased range of motion and mobility"
"[R]educe joint swelling and stiffness"
"500mg of msm fights inflammation, swelling, and pain impulses …."

Pamphlet claims-
"I have arthritis and fibromyalgia, and your joint formula helps both …."

Apple Cider Vinegar +

Pamphlet claims-
“Fenugreek … also may help to lower high cholesterol, triglyceride, and blood sugar levels.”

Colon Formula

Website claims-
“Relieve … constipation, and diarrhea”

Pamphlet claims-
“Bentonite… this potent detoxifier also helps clear out bad bacteria, viruses, mold, and pesticides”
“Apple fiber-the gentle cleanser that helps prevent constipation and diarrhea”
“Wheat grass … also helps remove drugs, heavy metals, and other toxins from your liver and blood”
“Rhubarb root …helps get rid of nasty parasites like pinworms, threadworms, and ringworms.”

Your products are not generally recognized as safe and effective for the above-referenced uses and, therefore, the products are “new drugs” under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(d), 355(a)]. FDA approves new drugs on the basis of scientific data and information demonstrating that the drug is safe and effective.

A drug is misbranded under section 502(f)(1) of the Act [21 U.S.C. 352(f)(1)] if the drug fails to bear adequate directions for its intended use(s). “Adequate directions for use” means directions under which a layperson can use a drug safely and for the purposes for which it is intended (21 CFR 201.5). Prescription drugs, as defined in section 503(b)(1)(A) of the Act [21 U.S.C. 353(b)(1)(A)], can only be used safely at the direction, and under the supervision, of a licensed practitioner.

Your Eterni-D and Apple Cider Vinegar products are intended for treatment or prevention of one or more diseases that are not amenable to self-diagnosis, treatment, or prevention without the supervision of a licensed practitioner. Therefore, it is impossible to write adequate directions for a layperson to use your products safely for their intended purposes. Accordingly, your Eterni-D and Apple Cider Vinegar+ products fail to bear adequate directions for their intended use and, therefore, the products are misbranded under section 502(f)(1) of the Act [21 U.S.C. 352(f)(1)]. The introduction or delivery for introduction into interstate commerce of this misbranded drug violates section 301(a) of the Act [21 U.S.C. 331(a)].

Misbranded Dietary Supplement

The dietary supplement products discussed below are misbranded within the meaning of Section 403 [21 U.S.C. § 343] of the Act because they fail to comply with the regulations implementing the food labeling requirements of the Act for dietary supplements, found in 21 CFR Part 101. Additionally, even if your Eterni-D, Colon Formula, and Apple Cider Vinegar+ products did not have therapeutic claims which make them unapproved new drugs and misbranded drugs, these products would be misbranded dietary supplements within the meaning of Section 403 of the Act for the reasons described below.

1. Your Eterni-D product is misbranded within the meaning of section 403(a)(1) of the Act [21 U.S.C. § 343(a)(1)] in that the product labeling is false and misleading. Specifically, your mail delivered pamphlet states “Eterni-D is manufactured in an FDA-approved lab under strict quality control guidelines”; however, the FDA does not approve dietary supplement labs or manufacturing facilities.

2. Your Mind and Memory Formula product is misbranded within the meaning of section 403(u) of the Act [21 U.S.C. § 343(u)] in that it purports to contain ginseng, but the purported ginseng ingredient is not from a plant classified within the genus Panax. Specifically, your product contains an ingredient identified as Siberian Ginseng (Eleutherococcus senticosus). That ingredient may not be declared under a name that includes the term "ginseng" because it is not from the genus Panax.

3. Your Eterni-D product is misbranded within the meaning of section 403(i)(2) of the Act [21 U.S.C. § 343(i)(2)] in that the product label fails to declare the common or usual names of each ingredient used as required 21 CFR 101.4. Specifically, we note in your label for the Eterni-D product you list ‘Opadryl II 57U92578 coating’, which is not the common or usual name of an ingredient.

4. Your Colon Formula product is misbranded within the meaning of section 403(q)(1)(A) of the Act [21 U.S.C. § 343(q)(1)(A)] because the serving size declared on the labels is incorrect. The terms "serving" or "serving size" for a dietary supplement are defined in 21 CFR 101.9(b) and 21 CFR 101.12(b) Table 2, as the maximum amount recommended on the label for consumption per eating occasion. The label has a serving size of 2 capsules; however, the directions state “take one (1) capsule twice daily.” Therefore, the label does not list the serving size appropriately.

5. Your Colon Formula and Apple Cider Vinegar+ products are misbranded within the meaning of section 403(s)(2)(C) of the Act [21 U.S.C. § 343(s)(2)(C)] because the labels fail to identify the part of the plant (e.g., root, leaves) from which each botanical dietary ingredient in the product is derived, as required by 21 CFR 101.4(h)(1).

The violations cited in this letter are not intended to be an all-inclusive list of violations that exist in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in enforcement action without further notice, including, without limitation, seizure and/or injunction.

Within fifteen (15) working days of receipt of this letter, please notify this office in writing of the specific steps you have taken to correct the violations noted above. Your response should include any documentation that would assist in evaluating your corrections. If you cannot complete corrective action within fifteen working days, please explain the reason for the delay and the date by which you will make the correction.

Your response should be sent to U.S. Food and Drug Administration, Lauren Crivellone, Compliance Officer, Food and Drug Administration, 550 West Jackson Boulevard, Suite 1500, Chicago, IL 60661. If you have any questions with regards to this letter, please contact Lauren Crivellone at (312) 596-4157 or email **lauren.crivellone@fda.hhs.gov (mailto:lauren.crivellone@fda.hhs.gov)**.

Sincerely,
/S/

William R. Weissinger, MS
Chicago District Director
Office of Human and Animal Food Operations
Division East 6

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